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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,510	06/02/2000	William G. Skelly	503775.008	7522

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/586,510	SKELLY, WILLIAM G.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see enclosed action.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see enclosed action*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-15*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1644

1. Claims 1-15 are under consideration. In view of the amended claim 1, the prior art rejection has been withdrawn and the previously withdrawn species are now under consideration.

2. In view of the papers filed 10/14/2003 and 2/11/2003, the inventorship in this nonprovisional application has been changed by the deletion of Harry Lenau.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

3. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants arguments have been considered and deemed not persuasive.

The specification is not enabling for the claimed method of treating exercise induced pulmonary hemorrhage (EIPH) recited in claim 1. The specification does not disclose how to use the instant invention for treating EIPH in vivo. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification. Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed

invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not

'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The state of the art is such that is unpredictable in the absence of any evidence as to how the instant invention could be used for the treatment of EIPH. As per Wands factor (3), the specification provides no working examples indicating that the method of the instant invention can be used for the treatment of EIPH. Erickson et al. teach that while

the cause of EIPH is unclear, it appears to involve stress failure of pulmonary capillaries(see pages 53 and 54). There is no evidence of record to suggest that IgG administration would have any effect on stress failure of pulmonary capillaries. Thus, it would be unpredictable as to whether IgG could be used to treat EIPH because there is no evidence of record to establish that IgG has any effect on stress failure of pulmonary capillaries. Thus, as per Wands factors (5) and (7), there is a high degree of unpredictability in the art and the prior art does not disclose evidence indicating that IgG can be used to treat EIPH. Furthermore, to the extent that the claims encompass Ig administration other than Ig, Hillidge et al. teach that IgE levels are actually increased in horses suffering from EIPH (see abstract). Based on the aforementioned undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification and the prior art alone. See In re Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404.

Regarding applicants comments, the Sheldon II declaration does not address EIPH and is therefore not germane to the instant rejection. Regarding the Erickson II declaration, additional information is required in order to fully evaluate the comments made in said declaration. Regarding point 8, a description of what specific Ig composition was used (a variety of different compositions are referred to in the "background section" of the instant application), how it was administered, when it was administered, what were the nature of controls used and what dosages were used is needed in order to determine the relevance of the experiments referred to in comparison to the disclosure of the specification and the scope of the claimed invention.

Regarding the Erickson III declaration , to the extent that the claims encompass Ig administration other than Ig, Hillidge et al. teach that IgE levels are actually increased in horses suffering from EIPH (see abstract). There is no evidence supplied in the Erickson III declaration that IgE could be used to treat EIPH. In addition, whilst the Erickson III declaration provides evidence that Seramune Equine IgG can be used to treat EIPH in horses, the evidence in section 10 of said declaration indicates that the aforementioned treatment does not prevent EIPH (as per recited in the current claims).

Furthermore, the Erickson declaration, paragraphs 12 and 13 seems to indicate use of "species-specific Ig for treating EIPH" whilst the instant claims (except for the recitation of IgG_t) are not restricted to the use of species specific antisera. In view of the uncertainty in the art as to the mechanism of action of the claimed invention (as per paragraph 15 of Erickson III) it is unclear whether species specific Ig is required for use in the claimed invention to obtain the results described in Erickson III. Similarly it is also unclear whether Ig other than IgG could be used in the claimed invention. It is also noted that the Erickson declaration discloses use of a particular dosage and means of administration wherein the combination of dosage and administration means are not recited in the current claims.

4. The rejection of claims 1,5,6,13-15 under 35 U.S.C. 102(a) as being anticipated by Ragland et al. is withdrawn because the method of the amended claims (drawn to treatment of EIPH in horses) is not disclosed by Ragland et al. The Skelly II declaration has not been considered because the amended claims are not anticipated by the Ragland et al. reference.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
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Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644